

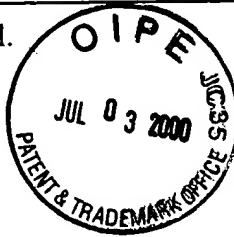
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Pepicelli et al.

Serial No.: 09/394,020

Filed: September 10, 1999

For: *Regulation of Lung Tissue by Hedgehog-Like Polypeptides, and Formulations and Uses Related Thereto*



Examiner: Janet Andres

Group Art Unit: 1642

Attorney Docket No.: HUV-032.01

#12  
/118

Assistant Commissioner for Patents  
Washington, D.C. 20231

**Certificate of First Class Mailing**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date set forth below.

June 30, 2000

By:

C. Eugene Coker

Date of Signature and Mail Deposit

**Response to Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures**

Dear Sir:

In response to the Office Communication dated January 28, 2000 in the above-referenced application, Applicants submit herewith a paper copy and computer readable form of a substitute Sequence Listing. A copy of the Notice to Comply is also included.

In accordance with §1.821(f), I hereby state that the information recorded in computer readable form on the enclosed diskette is identical to that in the paper copy of Sequence Listing enclosed herein.

In accordance with §1.821(g), I hereby state that the sequences contained in this sequence listing are supported in the application as filed. Neither the paper copy, nor the computer readable form of the Sequence Listing contains new matter.

If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

Respectfully submitted,  
FOLEY, HOAG & ELIOT LLP



---

Isabelle M. Clauss, Ph.D.  
Attorney for Applicants  
Reg. No. (*see attached*)

Patent Group  
FOLEY, HOAG & ELIOT LLP  
One Post Office Square  
Boston, MA 02109  
(617) 832-1000

Date: June 30, 2000



Application No.: 09/394020

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: \_\_\_\_\_

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support (SIRA)

Technical Assistance.....703-308-6900

To Purchase PatentIn Software.....703-306-2600

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09394020	09/10/99	Pepicelli	HUV-032.01

EXAMINER	
Janet Andres, Ph.D.	
ART UNIT	PAPER NUMBER
1642	10

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application  
Commissioner of Patents

The sequence filed on 09/10/99 is not fully compliant for the reasons set forth on the attached Notice to Comply with the Sequence Rules or CRF diskette problem report.

Since the filing appears to be bona fide, but through an apparent oversight or inadvertence failed to comply, APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.136(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703)305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell, can be reached at (703)308-2731. The fax phone number for this Group is (703)305-3014 or (703)308-4242.

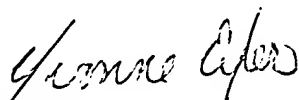
Communications via Internet email regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the

Interim Usernet Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Janet Andres  
Patent Examiner  
01/27/00

  
YVONNE EYLER, PH.D.  
PRIMARY EXAMINER

Andres

APPLICANT COPY

1642

1646

PAGE: 1

RAW SEQUENCE LISTING  
PATENT APPLICATION US/09/394,020

DATE: 01/10/2000  
TIME: 23:57:41

INPUT SET: S34406.raw

This Raw Listing contains the General  
Information Section and those Sequences  
containing ERRORS.

SEQUENCE LISTING

(1) General Information:

Does Not Comply  
Corrected Diskette Needed

(i) APPLICANT: Pepicelli, Carmen V  
Lewis, Paula M  
McMahon, Andrew P

(ii) TITLE OF INVENTION: Regulation of Lung Tissue by  
Hedgehog-like Polypeptides, and Formulations and Uses  
Related Thereto

(iii) NUMBER OF SEQUENCES: 24

(iv) CORRESPONDENCE ADDRESS:

(A) ADDRESSEE: Foley, Hoag & Eliot, llp  
(B) STREET: One Post Office Square  
(C) CITY: Boston  
(D) STATE: MA  
(E) COUNTRY: USA  
(F) ZIP: 02109

(v) COMPUTER READABLE FORM:

(A) MEDIUM TYPE: Floppy disk  
(B) COMPUTER: IBM PC compatible  
(C) OPERATING SYSTEM: PC-DOS/MS-DOS  
(D) SOFTWARE: ASCII(text)

(vi) CURRENT APPLICATION DATA: *US 09/394,020*

(A) APPLICATION NUMBER: ~~US 60/099,952~~ → *do not insert prior application*

(B) FILING DATE: ~~10-SEP-1999~~ *OK*

(C) CLASSIFICATION:

*number in  
Current  
Application  
Data section*

(vii) PRIOR APPLICATION DATA:

(A) APPLICATION NUMBER: US 60/099,952  
(B) FILING DATE: 11-SEP-1999 *8*

(viii) ATTORNEY/AGENT INFORMATION:

(A) NAME: Vincent, Matthew P  
(B) REGISTRATION NUMBER: 36,709  
(C) REFERENCE/DOCKET NUMBER: HUV-032.01

(ix) TELECOMMUNICATION INFORMATION:

(A) TELEPHONE: (617) 832-1000  
(B) TELEFAX: (617) 832-7000

INPUT SET: S34406.raw

46

## ERRORED SEQUENCES FOLLOW:

947 (2) INFORMATION FOR SEQ ID NO:8:

948

949

(i) SEQUENCE CHARACTERISTICS:

950

(A) LENGTH: 1191 base pairs

951

(B) TYPE: nucleic acid

952

(C) STRANDEDNESS: both

953

(D) TOPOLOGY: linear

954

955

(ii) MOLECULE TYPE: cDNA

956

957

958

(ix) FEATURE:

959

(A) NAME/KEY: CDS

960

(B) LOCATION: 1..1191

961

962

963

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:8:

964

965

ATG GCT CTC CTG ACC AAT CTA CTG CCC TTG TGC TGC TTG GCA CTT CTG

48

966

Met Ala Leu Leu Thr Asn Leu Leu Pro Leu Cys Cys Leu Ala Leu Leu

967

1

5

10

15

968

969

GCG CTG CCA GCC CAG AGC TGC GGG CCG GGC CGG GGG CCG GTT GGC CGG

96

970

Ala Leu Pro Ala Gln Ser Cys Gly Pro Gly Arg Gly Pro Val Gly Arg

971

20

25

30

972

973

CGC CGC TAT GCG CGC AAG CAG CTC GTG CCG CTA CTC TAC AAG CAA TTT

144

974

Arg Arg Tyr Ala Arg Lys Gln Leu Val Pro Leu Leu Tyr Lys Gln Phe

975

35

40

45

976

977

GTG CCC GGC GTG CCA GAG CGG ACC CTG GGC GCC AGT GGG CCA GCG GAG

192

978

Val Pro Gly Val Pro Glu Arg Thr Leu Gly Ala Ser Gly Pro Ala Glu

979

50

55

60

980

981

GGG AGG GTG GCA AGG GGC TCC GAG CGC TTC CGG GAC CTC GTG CCC AAC

240

982

Gly Arg Val Ala Arg Gly Ser Glu Arg Phe Arg Asp Leu Val Pro Asn

983

65

70

75

80

984

985

TAC AAC CCC GAC ATC ATC TTC AAG GAT GAG GAG AAC AGT GGA GCC GAC

288

986

Tyr Asn Pro Asp Ile Ile Phe Lys Asp Glu Glu Asn Ser Gly Ala Asp

987

85

90

95

988

989

CGC CTG ATG ACC GAG CGT TGC AAG GAG AGG GTG AAC GCT TTG GCC ATT

336

990

Arg Leu Met Thr Glu Arg Cys Lys Glu Arg Val Asn Ala Leu Ala Ile

991

100

105

110

992

# RAW SEQUENCE LISTING PATENT APPLICATION US/09/394,020

DATE: 01/10/2000  
TIME: 23:57:42

INPUT SET: S34406.raw

993	GCC GTG ATG AAC ATG TGG CCC GGA GTG CGC CTA CGA GTG ACT GAG GGC	384
994	Ala Val Met Asn Met Trp Pro Gly Val Arg Leu Arg Val Thr Glu Gly	
995	115 120 125	
996		
997	TGG GAC GAG GAC GGC CAC CAC GCT CAG GAT TCA CTC CAC TAC GAA GGC	432
998	Trp Asp Glu Asp Gly His His Ala Gln Asp Ser Leu His Tyr Glu Gly	
999	130 135 140	
1000		
1001	CGT GCT TTG GAC ATC ACT ACG TCT GAC CGC GAC CGC AAC AAG TAT GGC	480
1002	Arg Ala Leu Asp Ile Thr Thr Ser Asp Arg Asp Arg Asn Lys Tyr Gly	
1003	145 150 155 160	
1004		
1005	TTG CTG GCG CGC CTC GCA GTG GAA GCC GGC TTC GAC TGG GTC TAC TAC	528
1006	Leu Leu Ala Arg Leu Ala Val Glu Ala Gly Phe Asp Trp Val Tyr Tyr	
1007	165 170 175	
1008		
1009	GAG TCC CGC AAC CAC GTC CAC GTG TCG GTC AAA GCT GAT AAC TCA CTG	576
1010	Glu Ser Arg Asn His Val His Val Ser Val Lys Ala Asp Asn Ser Leu	
1011	180 185 190	
1012		
1013	GCG GTC CGG GCG GGC GGC TGC TTT CCG GGA AAT GCA ACT GTG CGC CTG	624
1014	Ala Val Arg Ala Gly Gly Cys Phe Pro Gly Asn Ala Thr Val Arg Leu	
1015	195 200 205	
1016		
1017	TGG AGC GGC GAG CGG AAA GGG CTG CGG GAA CTG CAC CGC GGA GAC TGG	672
1018	Trp Ser Gly Glu Arg Lys Gly Leu Arg Glu Leu His Arg Gly Asp Trp	
1019	210 215 220	
1020		
1021	GTT TTG GCG GCC GAT GCG TCA GGC CGG GTG GTG CCC ACG CCG GTG CTG	720
1022	Val Leu Ala Ala Asp Ala Ser Gly Arg Val Val Pro Thr Pro Val Leu	
1023	225 230 235 240	
1024		
1025	CTC TTC CTG GAC CGG GAC TTG CAG CGC CGG GCT TCA TTT GTG GCT GTG	768
1026	Leu Phe Leu Asp Arg Asp Leu Gln Arg Arg Ala Ser Phe Val Ala Val	
1027	245 250 255	
1028		
1029	GAG ACC GAG TGG CCT CCA CGC AAA CTG TTG CTC ACG CCC TGG CAC CTG	816
1030	Glu Thr Glu Trp Pro Pro Arg Lys Leu Leu Leu Thr Pro Trp His Leu	
1031	260 265 270	
1032		
1033	GTG TTT GCC GCT CGA GGG CCG GCG CCC GCG CCA GGC GAC TTT GCA CCG	864
1034	Val Phe Ala Ala Arg Gly Pro Ala Pro Ala Pro Gly Asp Phe Ala Pro	
1035	275 280 285	
1036		
1037	GTG TTC GCG CGC CGG CTA CGC GCT GGG GAC TCG GTG CTG GCG CCC GGC	912
1038	Val Phe Ala Arg Arg Leu Arg Ala Gly Asp Ser Val Leu Ala Pro Gly	
1039	290 295 300	
1040		
1041	GGG GAT GCG CTT CGG CCA GCG CGC GTG GCC CGT GTG GCG CGG GAG GAA	960
1042	Gly Asp Ala Leu Arg Pro Ala Arg Val Ala Arg Val Ala Arg Glu Glu	
1043	305 310 315 320	
1044		
1045	GCC GTG GGC GTG TTC GCG CCG CTC ACC GCG CAC GGG ACG CTG CTG GTG	1008



RAW SEQUENCE LISTING  
PATENT APPLICATION US/09/394,020DATE: 01/10/2000  
TIME: 23:57:42

INPUT SET: S34406.raw

1046	Ala Val Gly Val Phe Ala Pro Leu Thr Ala His Gly Thr Leu Leu Val	
1047	325 330 335	
1048		
1049	AAC GAT GTC CTG GCC TCT TGC TAC GCG GTT CTG GAG AGT CAC CAG TGG	1056
1050	Asn Asp Val Leu Ala Ser Cys Tyr Ala Val Leu Glu Ser His Gln Trp	
1051	340 345 350	
1052		
1053	GCG CAC CGC GCT TTT GCC CCC TTG AGA CTG CTG CAC GCG CTA GGG GCG	1104
1054	Ala His Arg Ala Phe Ala Pro Leu Arg Leu Leu His Ala Leu Gly Ala	
1055	355 360 365	
1056		
1057	CTG CTC CCC GGC GGG GCC GTC CAG CCG ACT GGC ATG CAT TGG TAC TCT	1152
1058	Leu Leu Pro Gly Gly Ala Val Gln Pro Thr Gly Met His Trp Tyr Ser	
1059	370 375 380	
1060		
--> 1061	CGG CTC CTC TAC CGC TTA GCG GAG GAG CTA CTG GGC TG	1191
1062	Arg Leu Leu Tyr Arg Leu Ala Glu Glu Leu Leu Gly	
1063	385 390 395	1190
1064		
1065		
1066		

---

PAGE: 1

**SEQUENCE VERIFICATION REPORT**  
**PATENT APPLICATION US/09/394,020**

DATE: 01/10/2000  
TIME: 23:57:42

*INPUT SET: S34406.raw*

Line	Error	Original Text
30	Wrong application Serial Number	(A) APPLICATION NUMBER: US 09/099,952
950	Entered (1191) and Calc. Seq. Length (1190) differ	(A) LENGTH: 1191 base pairs
1061	# of Sequences for line conflicts w/ running total	CGG CTC CTC TAC CGC TTA GCG GAG GAG CTA CT